IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE PLAVIX® MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	:	MDL NO. 2418
UNITED STATES OF AMERICA *ex rel.* JKJ PARTNERSHIP 2011 LLP, *et al*., *Plaintiffs,*	:	Civil Action No: 3:11-CV-6476-FLW-LHG
	:	FILED ELECTRONICALLY
v.	:	
SANOFI-AVENTIS U.S. LLC, et al., *Defendants*.	:	

PLAINTIFF-RELATOR'S COMBINED MEMORANDUM: IN OPPOSITION TO DEFENDANTS' (THIRD) MOTION TO DISMISS SECOND AMENDED COMPLAINT; AND IN SUPPORT OF ITS CROSS-MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT

W. Scott Simmer*
Gerald C. Robinson, NJ Lic. 028452005
Andrew M. Miller*
SIMMER LAW GROUP PLLC
The Watergate, Suite 10-A
600 New Hampshire Ave, NW
Washington, DC 20037
Telephone: (202) 333-7352
Facsimile: (202) 337-1039

William H. Narwold*
Michael J. Pendell*
Laura W. Ray*
MOTLEY RICE LLC
One Corporate Center, 20 Church St., 17th Flr
Hartford CT 06103
Telephone: (860) 882-1676

Nathan D. Finch*
MOTLEY RICE LLC
3333 K St. NW, Suite 450
Washington DC 20007
Telephone: (202) 232-5507

*Admitted *pro hac vice*

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INTRODUCTION

In their third iteration[1] of a motion to dismiss the Second Amended Complaint ("SAC"), Defendants assert that—as a partnership formed for the purpose of bringing this action under the False Claims Act ("FCA")[2]—Relator JKJ Partnership 2011 ("JKJ" or "Relator")[3] is an improper relator because it lacks Article III standing, cannot qualify as an original source, no longer exists due to the substitution of one of its partners, and cannot cure these defects by joining its individual partners as relators. Defendants are wrong as a matter of law and fact.

ARGUMENT

I. ARTICLE III STANDING

In the context of an FCA action, Congress conferred capacity to sue upon all legal persons by stating, without qualification, that "[a] person may bring a civil action for a violation of section 3729 *for the person* and for the United States Government," 31 U.S.C. § 3730(b)(1) (emphasis added), against "[a]ny person" who, *inter alia*, "knowingly presents … to … the … Government … a false or fraudulent claim for payment. 31 U.S.C. § 3729(a)(1)(A).

The Supreme Court has held that a relator has Article III standing because they sue both for the Government's interest and for their own interest as partial assignee of the Government's

[1] Defendants served, but did not file, their first iteration on April 24, 2017 (hereafter "Defs.' 4/24/17 Mem."), to which Relator similarly served, but did not file, an opposition on June 8, 2017. Shortly thereafter, the Court dismissed with prejudice the other Plavix FCA action. *U.S. ex rel. Dickson v. Bristol-Myers Squibb Co.*, No. 3:13-CV-1039, 2017 WL 2780744 (D.N.J. June 27, 2017) ("*Dickson IV*"). At that day's Status Conference, the Court directed Defendants in the instant action to re-brief their motion to dismiss in light of *Dickson IV*. Thereafter, Defendants served, but did not file, a second iteration on August 4, 2017 (hereafter "Defs.' 8/4/17 Mem."). At the August 9, 2017 Status Conference, Your Honor requested that Defendants file, by August 25, 2017, a more limited motion to dismiss fully addressing whether JKJ—as a partnership formed for the purpose of bringing this action—is a proper relator. (hereafter "Defs.' 8/29/17 Mem.").

[2] 31 U.S.C. § 3729, *et seq.*

[3] JKJ Partnership 2011 ("JKJ" or "Relator") is a Delaware limited partnership comprised of partners Dr. Paul Gurbel, Dr. Jeffrey Stahl, and Ms. Kelly Evans Wood, each of whom has first-hand knowledge of Defendants' unlawful marketing scheme detailed in the SAC.

interest—in the form of a statutory reward measured as a percentage of the Government's recovery. *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2007). The Court also noted that the relator's interest is inchoate and "does not even fully materialize until the litigation is completed and the relator prevails." *Id*.

Importantly, neither Congress nor the Supreme Court placed any legal status restrictions—such as being a natural person or a U.S. citizen—on the type of legal "person" permitted to perfect the statutorily granted inchoate partial assignment. Federal Rule of Civil Procedure 17 further supports the ability of an association or partnership to enforce rights conferred by federal statute.[4] As a result, successful FCA actions have been brought by natural persons,[5] associations,[6] partnerships,[7] and even corporations.[8] In fact, on August 17, 2017, the Department of Justice ("DOJ") announced that one of the corporate Defendants in the present case, Sanofi-Aventis US LLC, served as a relator in an FCA action against a competitor, recovering $465 million for the Government and yielding a $38.7 million reward to Sanofi-Aventis.[9]

Ignoring the foregoing, Defendants argue that JKJ lacks Article III standing because it cannot satisfy the "associational standing" criteria articulated for unincorporated associations in *Hunt v.*

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[4] Rule 17 first allows actions to be brought by "a party authorized by statute," such as the FCA here. Fed. R. Civ. P. 17(a)(1)(G). The Rule then specifically sweeps aside any state law impediments to a partnership's ability to proceed pursuant to such federal statutory authorization, stating "a partnership or other unincorporated association with no such capacity under that state's law may sue or be sued in its common name to enforce a substantive right existing under the United States Constitution or laws." *Id*. at 17(b)(3)(A).

[5] *E.g., U.S. ex rel. Atkinson v. P.A. Shipbuilding Co.*, 473 F.3d 506 (3d Cir. 2007).

[6] *E.g., Minnesota Ass'n of Nurse Anesthetists ("MANA") v. Allina Health Sys. Corp.*, 276 F.3d 1032 (8th Cir. 2002).

[7] *E.g., U.S. ex rel. Moore & Co., P.A., v. Majestic Blue Fisheries, LLC*, 812 F.3d 294 (3d Cir. 2016).

[8] *E.g., U.S. ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645 (D.C. Cir. 1994).

[9] https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates. The case was *United States ex rel. Sanofi-Aventis US LLC v. Mylan Inc. and Mylan Specialty L.P.*, No. 16-cv-11572-ADB (D. Mass.), originally filed on July 29, 2016.

Wash. State Apple Advert. Commn'n, 432 U.S. 333, 343 (1977). *See* Defs.' 8/29/17 Mem. at 10-12. In *Hunt* the Court articulated that "we have recognized that an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organizations' purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* Defendants here do not challenge the first or second requirements. Instead, noting the Third Circuit applies *Hunt* to partnerships,[10] Defendants here argue from inapposite cases to assert that JKJ cannot satisfy *Hunt's* third requirement because JKJ's partners must participate, either as fact witnesses to establish JKJ as an "original source," or because the litigation is really brought to enforce their unique individual rights. Defs.' 8/29/17 Mem. at 11-12.

Defendants cite to the inapposite case of *U.S. ex rel. Woods v. SouthernCare, Inc.*, No. 09-CV-313, 2013 WL 11836757, at *8 (S.D. Miss. July 5, 2013) for the unremarkable proposition that, when an action is brought by multiple individual relators, each relator must individually qualify as an "original source*." SouthernCare* does not support Defendants' position that, when a partnership or unincorporated association brings an FCA action, each of its members must qualify as an original source. Moreover, pursuant to Delaware law and JKJ's partnership agreement, JKJ "shall not be a separate legal entity distinct from its Partners." *See infra* Section II.C. Therefore, as an evidentiary matter, an association can only demonstrate its "direct" knowledge for "original

[10] Defs.' 8/29/17 Mem. at 10-12 (citing *Maiden Creek Assocs., L.P. v. U.S. Dep't of Transp.*, 123 F. Supp. 3d 638, 647 (E.D. Pa. 2015), *aff'd*, 823 F.3d 184 (3d Cir. 2016)). In *Maiden Creek*, the courts held that a partnership property owner and a township board only had standing to challenge proposed changes to a state highway to the extent they articulated "personalized harm," and lacked standing with respect to the interests of travelers along the route or hypothetical consumers of the partnership's proposed shopping center. 123 F. Supp. 3d at 647-48, *aff'd*, 823 F.3d 184. In contrast, here JKJ does not seek to represent the interests of strangers, but rather its own interests and those of its members with respect to the identical inchoate statutory right to sue on behalf of the Government Plaintiffs and claim the statutory reward.

source" purposes through the testimony of its members. *See, e.g., MANA*, 276 F.3d at 1049-50. This evidentiary participation, however, is not the type of "participation" contemplated by *Hunt*, which itself framed its holding in terms of whether the claims or relief requested required "individualized proof." *Hunt*, 432 U.S. at 344 (holding that a state agency with no members, had standing on behalf of Washington apple growers to challenge a North Carolina statute allowing display of only USDA apple grading scheme, effectively prohibiting display of any state level grading scheme). In the present case, no "individualized proof" is required because no individualized claims or remedies are raised—which goes straight to Defendants' second point addressed below.

Defendants' also assert this action is brought to enforce individual rights, which is wholly unsupported by the inapposite authority they cite.[11] In contrast, Relator has already demonstrated, *supra*, that JKJ and its members have the same undifferentiated, inchoate statutory interest granted by the FCA. *See, e.g., MANA*, 276 F.3d at 1049-50. This is especially true here where JKJ "shall not be a separate legal entity distinct from its Partners." *See infra* Section II.C. Hence, JKJ is not just an entity representing the interests of its partners, JKJ's interests are indistinguishable from those of its partners. In short, there is no impediment to JKJ's Article III standing.

II. THE SAC IS NOT BARRED BY THE FCA'S PUBLIC DISCLOSURE BAR

Defendants argue, incorrectly, that JKJ's claims are barred by the FCA's public disclosure bar. Defs.' 8/29/17 Mem. at 2-9. The public disclosure bar, however, is not triggered merely by the existence of some salient facts in the public domain, but by disclosure of all the elements of the fraud sufficient to support an FCA action—which did not occur here prior to this case being

[11] Defendants cite to *Pa. Psychiatric Soc. v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 286, 2002 WL 186008 (3d Cir. 2002) and *Franco v. Conn. Gen. Life Ins. Co.*, 647 F. App'x 76, 82083 (3d Cir. 2016). In those cases, unlike here, associational standing was inappropriate because the harm varied by member. *Id.*

unsealed. To avoid Third Circuit precedent, Defendants mis-frame the public disclosure bar to exclude Relator's critical allegations, then cite inapposite cases concerning corporations (rather than partnerships), to ineffectually argue JKJ cannot qualify as an original source—the exception to the public disclosure bar. Relator demonstrates below that, when properly analyzed, the scant information in the public domain is insufficient to trigger the public disclosure bar. Furthermore, even if the Court were to decide otherwise, JKJ properly qualifies as an "original source."

Procedurally, this Court applies the version of the public disclosure bar in force at the time claims for payment were submitted. *U.S. ex rel. Dickson v. Bristol-Meyers Squibb Co.*, 123 F. Supp. 3d 584, 595 (D.N.J. 2015) ("*Dickson III*"). There is, however, a procedural difference: because the pre-PPACA[12] public disclosure bar is "jurisdiction-stripping,"[13] evaluation is made under Fed. R. Civ. P. 12(b)(1); whereas, because the post-PPACA version is not jurisdictional,[14] evaluation is made under Fed. R. Civ. P. 12(b)(6). Either way, the analysis is made on a claim-by-claim basis. *U.S. ex rel. Merena v. SmithKline Beecham Corp.*, 205 F.3d 97, 102 (3d Cir. 2000).[15]

A. The Pre-PPACA Provision Does Not Bar JKJ's Claims

1. JKJ's Allegations Were Not "Publicly Disclosed"

Defendants assert that qualifying public disclosures effecting pre-PPACA claims occurred via pleadings publicly filed in 2011 in two Plavix personal injury cases styled *Hall v. Bristol-Myers Squibb Co.*, No. 3:06-cv-05203-FLW-TJB (D.N.J.) and *Mills v. Bristol-Myers Squibb Co.*, No.

[12] "PPACA" refers to the Patient Portability and Affordable Care Act, Pub.L. No. 111-148, 124 Stat. 119 (eff. Mar. 23, 2010).
[13] *Graham Cty Soil & Water Conserv. Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 285-86 (2010).
[14] *Dickson III*, 123 F. Supp. 3d at 594.
[15] As a preliminary matter, Relator notes that Defendants incorporate by reference the public disclosure arguments in their April 24, 2017 and August 4, 2017 memoranda, which they attach as Exhibits A and B.[15] Defs.' 8/29/17 Mem. at 3 n.2. Defendants do not, however, incorporate by reference their public disclosure arguments from the previous memoranda. *Id*.

2:11-CV-968-FJM-PHX (D. Ariz.), two or three[16] 2011 media reports concerning the court's decision in *Mills*, and one or two[17] media reports concerning an eventual 2009 FDA label change adding Plavix VOR information. Defs.' 8/29/17 Mem. at 4-5 and nn.4-6.

A qualifying "public disclosure" under the pre-PPACA version of the statute must issue from a source or occur in a context specifically recognized by the FCA as public information within the meaning of the Act. *U.S. ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 332-33 (3d Cir. 2005). Critically, as part of the pre-PPACA public disclosure analysis, the Court examines "whether the public disclosure contains 'allegations or transactions' of the fraud upon which the *qui tam* action is based," which requires "at least enough information underlying those allegations to articulate a legal claim." *Id.* at 334. Thereafter, the court determines "whether the current action is 'based upon' the public disclosure of the allegations or transactions of fraud," which requires a showing that the allegations in the current action are "substantially similar to" the publicly disclosed "allegations or transactions of fraud." *Id.* at 334-35.

Notably, Defendants fail to cite binding authority for determining whether a public disclosure of the allegations or transactions has occurred. *See U.S. ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 741 (3d Cir. 1997) (adopting *U.S. ex rel. Springfield Terminal Railway Co. v. Quinn*, 14 F.3d 645, 653-54 (D.C. Cir. 1994)). As set forth in *Springfield Terminal*, "the term 'allegation' connotes a conclusory statement implying the existence of provable supporting facts. The term 'transaction' suggests an exchange between two parties or things that reciprocally affect or influence each other." *Springfield Terminal*, 14 F.3d at 653-54. Therefore, "if X + Y = Z, Z

[16] In their first iteration of this motion, Defendants also included a third news article about the *Mills* decision. *See* 4/24/17 Rooney Decl. Ex.D.

[17] In their second iteration of this motion, Defendants also included a second news article reporting on an actual Plavix label change approved by the FDA in 2009. *See* 8/4/17 Rooney Decl. Ex. E.

represents the allegation of fraud and X and Y represent its essential elements." *Id.* at 654. "Congress sought to prohibit qui tam actions only when either the allegation of fraud or the critical elements of the fraudulent transaction themselves were in the public domain." *Id.*

Defendants' failure to address directly the analysis in *Springfield Terminal* is telling because the purported disclosures here do not disclose either the conclusion of fraud or the essential elements of the fraud alleged by JKJ. Hence, the public information cannot qualify as a "public disclosure." *See Springfield Terminal*, 14 F.3d at 655. Instead, Defendants reference the analysis through quotations lifted out of context to assert that "[t]o disclose an 'inference of fraud,' prior disclosures need only publicize a set of 'misrepresented facts' and a set of 'true facts.'" Defs.' 8/29/17 Mem. at 3 (citing *Dickson*, 123 F. Supp. 3d at 596 (quoting *U.S. ex rel. Atkinson v. P.A. Shipbuilding Co.*, 473 F.3d 506, 519 (3d Cir. 2007)). This mis-framing of the law—not requiring that the "misrepresented" and "true" set of facts disclose all the essential elements supporting an inference of the fraud alleged by relator—opens the door for Defendants to set up any dichotomy of true and misrepresented facts and assert that it qualifies as an FCA "public disclosure." This is exactly what Defendants next do in an effort to fit within the public disclosure framework of *Dickson III*—where, unlike here, there was no allegation that Defendants possessed and concealed knowledge of a safety or efficacy issue prior to the issue's revelation in a published article.[18]

[18] In *Dickson III*, the relator alleged that Defendants made representations about Plavix which were not supported by, or were contrary to, published studies. *See Dickson*, Dkt 112, Fourth Amended Complaint, at ¶¶ 4-20 and Ex. A. Critically, and unlike JKJ here, relator Dickson did not allege Defendants concealed proprietary data and analysis pre-dating the published studies. As a result, in *Dickson III* Defendants here framed the public disclosure issue in terms of its misrepresentations against the backdrop of its knowledge available from the published studies, stating:

> The public sources, including the *Hall* Complaint, cited above, discuss the findings of a study known as "CAPRIE," which compared Plavix to aspirin, and the "Chan study," which compared the effects of Plavix and aspirin on patients who previously had stomach ulcers, as well as FDA letters sent to Defendants; all the facts from the sources are presented in the TAC. Essentially, these sources indicate that Plavix is no more effective or safer than aspirin.

In particular, Defendants assert "[h]ere, the allegedly misrepresented fact is that Plavix® is effective regardless of patients' genetic variation, while the allegedly true fact is that Plavix® is less effective for patients with genetically reduced CYP2C19 function." Defs.' 8/29/17 Mem. at 4. Defendants then match their false scientific dichotomy to their assertions that "[t]he plaintiffs in *Hall* and *Mills* disclosed the allegedly 'true' and 'misrepresented' facts that JKJ alleges here: certain people exhibit reduced responsiveness to Plavix® due to genetic variability of response to the drug ('genetic VOR'), and Defendants did not disclose this genetic VOR, thus *implying* Plavix®'s effectiveness regardless of genetic variation." *Id*. (emphasis added). Defendants rest upon the same implication as to the news article(s) about the eventual 2009 FDA approval of a label change, which do not even mention that Defendants failed to disclose the VOR issue.

If, like *Dickson*, JKJ here had alleged Defendants simply misrepresented Plavix against the backdrop of published studies, then Defendants' framing of the public disclosure issue would be more accurate—although it would still only reveal that Defendants had knowledge of the truth, while failing to reveal whether Defendants violated the FCA by acting "knowingly" (*i.e.,* with at least reckless disregard of the truth),[19] rather than negligently. *See Dickson III*, 123 F. Supp. 3d at

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> To use the algebraic formula presented by the Third Circuit, the misrepresented facts (X) are Defendants' representations that Plavix is more effective and safer than aspirin; the true facts (Y) are that Plavix is neither more effective nor safer than aspirin. Both sets of facts are alleged in the public disclosures provided by Defendants. Thus, I find that the TAC is substantially similar to, and therefore based on, these public disclosures.

Dickson III, 123 F. Supp. 3d at 596-97. While Defendants' knowledge of the truth was self-evident from the published studies, Dickson protested that the "critical element" of scienter was not revealed, but failed to offer case law supporting such a requirement. *Id.* at 597. In *dicta*, the Court suggested that "the formulation given by the Third Circuit does not require that the public disclosures reveal any knowledge to implicate the public disclosure bar, nor does Relator cite to any cases to support her position." *Id.* JKJ respectfully submits, as supported *infra*, that the Third Circuit requires that the public disclosure reveal all the elements of fraud—including scienter.

[19] While colloquially referred to as an anti-fraud statute, the FCA's reach extends beyond the elements of common law fraud. With respect to scienter, the statute defines that "the terms 'knowing' and 'knowingly'—(A) mean that a person, with respect to information—(i) has actual

599 (concluding that *Hall* and the related news articles did not disclose the "essential elements of the fraudulent scheme," including scienter). But that is not the fraud alleged by JKJ. Therefore, Defendants' attempt to frame a public disclosure that bars JKJ's action fails to satisfy Third Circuit precedent. *See Atkinson*, 473 F.3d at 519 ("X and Y represent the **essential elements**" of Z, which is the legal conclusion of fraud alleged by relator) (emphasis added) (quoting *Springfield Terminal*, 14 F.3d at 654). As the Third Circuit previously clarified:

> We have held that the public disclosure of a "transaction[]" within that provision requires the disclosure of the 'elements of the underlying fraudulent transaction.' This means that the disclosure must reveal both the misrepresented state of facts and the true state of facts so that the inference of fraud may be drawn.

U.S. ex rel. Mistick PBT v. Housing Auth. Of City of Pittsburgh, 186 F.3d 376, 385 (3d Cir. 1999) (quoting *Dunleavy*, 123 F.3d at 740-41). Hence, it is not sufficient to juxtapose public information that is merely relevant to the FCA action. The facts and analysis in *Mistick* are instructive.

In *Mistick*, relator alleged false claims were submitted to HUD for lead abatement. *Id.* at 379-82. Consistent with its theory, the "elements of the underlying fraudulent transaction" necessarily included scienter, as reflected in the framing that "the true facts were (1) that the Glidden policy of not recommending Glid-Wall as a lead-based encapsulant was in effect before Astorino submitted the specifications and (2) that Astorino and the Authority were **aware** of the policy but **knowingly** represented otherwise to HUD." *Id.* (finding that the true set of facts were disclosed in a state court action and the misrepresentations to HUD were disclosed through a FOIA response).

Here, the bits of public information adduced by Defendants fail to reveal all of the required elements of alleging the fraud alleged by JKJ, where Defendants knowingly misrepresented Plavix

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knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud." 31 U.S.C. §3729(b)(1).

against the backdrop of knowledge it possessed prior to any publication of the VOR issue. A close comparison of the purported public disclosures to JKJ's allegations brings the point home.

First, *Hall* made one vague statement "that 'over 30% of people taking Plavix incur no benefit' as a result of 'genetic variability,' and that they asserted that Defendants 'knew [of the VOR issue] for many years' but did not disclose it until 2009." Defs.' 8/29/17 Mem. at 4 n.4.[20] At no place in *Hall*'s public record[21] did counsel, or this Court, identify the CYP2C19 low-responder issue, the Defendants' knowing misrepresentations related thereto, or how it affected Government Programs—*i.e.*, the allegations or transactions of fraud which only appear in the SAC. *Cf. Dickson III*, 123 F. Supp. 3d at 599 (public information failed to provide "essential elements of fraudulent scheme," such as scienter, how defendants promoted Plavix, and its effect on the Government).

Similarly, the *Mills* complaint asserted that "patients carrying a genetic variant of CYP incur a greater risk of adverse events." Defs.' 4/24/17 Mem. at 7. Defendants concede, however, such personal injury excessive bleeding cases are inapposite because "*bleeding* . . . is the exact opposite of what a patient with poor Plavix® response would experience." Defs.' 4/24/17 Mem. at 25 n.17. Recognizing this implausibility and the plaintiff's failure to satisfy Rule 9(b) specificity, that court denied as futile the proposed amendment. *Mills*, 2011 WL 4708850, at *2-3. Hence, in both *Hall*

[20] *See also* Defs.' 4/24/17 Mem. at 7.

[21] The *Hall* docket reveals that the related motion papers were not publicly filed, leaving only this Court's Order [Letter Order, ECF No. 106] and the transcript of the second hearing [Hr'g. Tr., ECF No. 105] as publicly available materials. Even so, defense counsel characterized plaintiffs' request as a "fishing expedition," Hr'g Tr. 26:6-7, noting that plaintiff's counsel had conceded that lack of efficacy was not relevant, *id*. 25:9-11, because excessive bleeding injuries [Hall suffered two strokes while taking Plavix] would only be linked to a genetic hyper-responder, and there was no evidence that any plaintiff fit that profile, *id*. 23:13-14.

and *Mills*, the plaintiffs failed to grasp the science, let alone how Defendants knowingly concealed, obfuscated and misrepresented that science and its impact on Government Programs.[22]

Critically, the information cited by Defendants discloses nothing about the true half of the story alleged by JKJ, a story where: Defendants' knew [redacted] that Plavix had no (or little) effect for many patients[23]; that [redacted] was of the same large, proprietary clinical studies used to obtain FDA approval, which studies used platelet aggregation testing on each participant to correlate the antiplatelet effects of Plavix to clinical outcomes[24]; that Defendants did not publicly disclose [redacted], and compounded that concealment by knowingly taking measures to prevent, delay, and/or obfuscate any independent research which included platelet aggregate testing of participants because it would reveal the VOR issue[25]; that, despite Defendants' external insistence that there was no conclusive evidence showing a correlation between non-response and clinical outcomes,[26] [redacted], SAC ¶ 186, even acknowledging that this was an [redacted], *id.* ¶ 253; that Defendants' [redacted] – *i.e.*,

[22] The *Mills* complaint cites Jessica L. Mega, *et al., Cytochrome P-450 Polymorphisms and Responses to Clopidogrel*, 360 NEJM 354-63 (Jan. 22, 2009), for the proposition that, as paraphrased by the court: "the chemical structure of Plavix is defective because it carries a higher risk of adverse events for patients who carry the genetic variant CYP, who are poor metabolizers of the drug." *Id.* at *2 and n.1. Importantly here, Mega specifically relied on two studies for which she acknowledged Dr. Gurbel was the principle investigator. *See* Gurbel PA, *et al*., *Clopidogrel for coronary stenting: response variability, drug resistance, and the effect of pretreatment platelet reactivity*, 107 Circulation 2908-13 (2003) (attached hereto as Exhibit A); and Gurbel PA, *et al*., *Clopidogrel effect on platelet reactivity in patients with stent thrombosis: results of the CREST Study*, 46 J. Am. Coll. Cardiol. 1827-32 (2005) (attached hereto as Exhibit B).

[23] SAC ¶¶ 9, 131-32, 139, 188, 208, 220, 222, 242, 249, 274, 368.

[24] SAC ¶¶ 131-32, 136, 187-88.

[25] SAC ¶¶ 131-32, 139-42, 149-51, 184-91.

[26] *Id*. ¶¶ 187, 215, 229, 231, 232, 234, 237, 241, 259, 273, 300.

[redacted] and [redacted] descent groups, for which Defendants knew Plavix was even more ineffective[27]; that Defendants knowingly engaged in a deceptive "[redacted]" scheme, *id*. ¶¶ 206-48, touting publicly the "proven" safety and efficacy of Plavix for all patients, despite knowing it had concealed, delayed and obfuscated the truth[28]; that Defendants knowingly and secretly engaged in an "[redacted]" scheme, promoting Plavix through false and misleading advertising that overstated efficacy and minimized critical adverse event and risk information, knowingly selling its safety and efficacy in *all* patients, in spite of the fact that [redacted] had shown otherwise. *Id.* ¶¶ 249-303.

As a matter of law, any negligible factual overlap between JKJ's allegations and *Hall* and *Mills* fails to support a finding that the latter qualify as "'allegations or transactions' of the fraud upon which the *qui tam* action is based," because they lack "both allegations of fraud . . . and at least enough information underlying those allegations to articulate a [FCA] legal claim." *Paranich*, 396 F.3d at 334[29]; *Dunleavy*, 123 F.3d at 740-41; *Atkinson*, 473 F.3d at 519. Accordingly, JKJ's current action cannot be "based upon" any publicly disclosed allegations or transactions of fraud, because no allegations or transactions of fraud were disclosed. As such, JKJ's action is not "substantially similar" to any prior "allegations or transactions" that were sufficient to articulate a legal claim under the FCA. *Paranich*, 396 F.3d at 334-35.

[27] *Id*. ¶¶ 2, 5, 158, 211, 272, 274-80, 285.
[28] *Id*. ¶¶ 240, 262, 269, 274-75, 277, 280.
[29] As a point of comparison, the present case is unlike *Paranich*, where a prior complaint contained enough information to articulate a legal claim of fraud on the Government because it alleged that a medical device maker induced purchases by "misrepresenting to the class members that MEDICARE will pay for treatments given patients with this device…. In truth, MEDICARE now claims that the billings for treatments rendered by the device were erroneous and in violation of MEDICARE Law." *Id*. at 335.

2. JKJ Is an "Original Source" Under the Pre-PPACA FCA

Relevant here, under pre-PPACA jurisprudence, JKJ is an original source because it: "had (1) *direct* and (2) *independent* knowledge of the information on which the allegations are based," and (3) satisfied the pre-filing disclosure requirement. *Paranich*, 396 F.3d at 335.[30]

As a threshold matter, Defendants challenge whether an entity such as JKJ can have any "direct" knowledge at all. Defs.' 8/29/17 Mem at 6-7. It is unquestioned that an entity whose legal status is not separate from its members can serve as a relator and have the requisite knowledge to be an original source. *See, e.g.*, *MANA*, 276 F.3d at 1048-450; *see also Majestic Blue*, 812 F.3d at 296. In *MANA*, the Eighth Circuit noted that "[n]either the 1986 Amendments Act nor a review of its background or legislative history suggests that Congress meant to exclude suits on the basis of whether the relator was a natural person, corporation, or association." *Id.* at n.12.

The present case is closely aligned with *MANA*, since JKJ is a Delaware limited liability partnership whose legal status and knowledge are not separate from its members'. SAC ¶¶ 26-27. *See Rehoboth Mall Ltd. Partnership v. Eckerd Corp.*, C.A. No. 05C-12-025, 2006 WL 3308213, at *3 (Del. Super. Ct., Sussex Cty, Oct. 16, 2006) (under Delaware Revised Uniform Partnership Act ("DRUPA"), "[a] partner's knowledge, notice or receipt of a notification of a fact relating to the partnership is effective immediately as knowledge by, notice to, or receipt of a notification by the partnership") (citing DEL. CODE ANN. tit. 6, § 15-102); *see also* DEL. CODE ANN. tit. 6, § 15-

[30] On October 31, 2011, prior to filing its original complaint, JKJ provided to the Attorney Generals of the United States and the States substantially all the evidence and information material to the action. *See* SAC ¶ 22. Also, prior to filing the SAC, JKJ provided Government prosecutors substantially all the new evidence and information material to the amended complaint, including the allegations referencing MDL documents. Hence, contrary to Defendants' speculation, Defs.' 8/29/17 Mem. at n.8, the Government was afforded its statutory right to have the SAC filed under seal to permit the Government to conduct a covert investigation. *See* Declaration of Scott Simmer ¶¶ 6-9; *U.S. ex rel. Mikes v. Straus*, 931 F. Supp. 248, 259-60 (S.D.N.Y.1996) (openly filed amended FCA complaint did not deprive government of its rights where it received prior notice).

1206 (DRUPA applies to all partnerships on and after Jan. 1, 2002, necessarily including limited liability partnerships formed under DEL. CODE ANN. tit. 6, § 15-1001).

Ignoring these critical distinctions, Defendants cite inapposite cases for the unremarkable proposition that a corporate entity does not gain the knowledge held by its shareholders. Defs.' 8/29/17 Mem. at 6-7.[31] However, by its very nature, the corporation is set up to shield the shareholders from liability, *Agar v. Judy*, 151 A.3d 456, 488 (Del. Ch. 2017) (unincorporated associations, including partnerships, are "not an entity like a corporation which exists apart from people" and "[i]ts membership does not share the insulation from personal liability as shareholders"), so it is no surprise that these cases hold that the corporation's knowledge is distinct from the shareholder's knowledge. *Crites v. Photometric Products Corp.*, 169 A. 164, 167 (Del. Ch. 1933) (corporation's knowledge is not mercurial with the shifting of its personnel). That's a far cry from the JKJ partnership, which is not a separate legal entity distinct from its partners, and therefore JKJ's knowledge is identical to that of its partners.

Here, JKJ is endowed with direct knowledge from its partners' individual involvement in aspects of the allegations. Dr. Gurbel endows JKJ with direct knowledge because he was at the forefront of research into the VOR issue and published numerous articles on the topic.[32] Dr. Gurbel also learned first-hand—from the Defendants themselves—that they were unwilling to support research studies that included an antiplatelet testing protocol. *Id.* ¶¶ 134, 136, 140. Such research

[31] Defendants cite to *Federal Recovery Services, Inc. v. U.S.*, 72 F.3d 447, 451 (5th Cir. 1995), and *U.S. ex rel. Precision Co. v. Koch Indus., Inc.*, 971 F.2d 548, 554 (10th Cir. 1992) ("*Precision Co. I*"), where *corporations* were formed for the sole purpose of bringing FCA actions. Those cases are inapposite because the Relator here is a *partnership*. *MANA*, 276 F.3d at 1049-50. Defendants also ignore the Tenth Circuit's subsequent decision, where it allowed joinder of one of *Precision Co.'s* shareholder as an individual relator. *U.S. ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1017 (10th Cir. 1992) ("*Precision Co. II*") (discussed *infra*, Section III.E.).

[32] SAC ¶¶ 28, 131-44, 155-59, 187, 221, 229, 231, 244.

would have definitively correlated Plavix responsiveness with clinical outcomes and led to refined prescribing of Plavix for only patients with appropriate responsiveness. It is precisely this interference and usurpation of independent medical judgment that drove Dr. Gurbel to continue his own Plavix studies and ultimately led him to come forward here. Despite their misconduct (or maybe because of it), Defendants now proudly raise as a legal shield the very deceit they perpetrated—asserting that the science concerning clinical outcomes is too uncertain to support an FCA action. Mem. 15-17. Internally, they adopted an entirely different position. SAC ¶¶ 186, 253.

Meanwhile, Ms. Evans endows JKJ with direct knowledge as "[t]he paradigmatic . . . whistleblowing insider." *See U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1161 (3d Cir. 1991); *Dickson III*, 123 F. Supp. 3d at 599 (finding sales rep. relator had direct knowledge). As a Plavix sales representative and sales trainer from 2006 to 2010, SAC ¶ 30, Ms. Evans gained first-hand knowledge of Defendants' marketing and promotion practices, including, *inter alia*, the ACS Strong Start and other marketing campaigns. *Id*. ¶¶ 267-90. Ms. Evans also learned first-hand of Defendants' directives to the sales force to downplay the benefits of testing while pushing to get patients on Plavix at earlier stages of care—including pushing adoption of Plavix as a protocol in emergency rooms (which, due to the resulting bleed risk, foreclosed surgical interventions and locked patients into a Plavix regimen), by informing concerned physicians that they could simply double the dose of Plavix to avoid the non-responder issue. *Id*. ¶¶ 267-70, 287, 289-90, 294, 368-69, 372.

Dr. Stahl likewise endows JKJ with direct knowledge because he was a physician who received Defendants' false and misleading promotions concerning Plavix. *See Paranich*, 396 F.3d at 336 (relator had "direct knowledge of the billing scheme because he was *involved* in it" as a target of defendant's off-label promotions) (emphasis in original). In the present case, Dr. Stahl

was a high-volume Plavix prescriber who for many years received at least weekly presentations by Defendants' sales representatives promoting the appropriateness of Plavix for *all* patients in need of antiplatelet therapy. SAC ¶¶ 181-82, 281-85.

The Third Circuit interprets the "independent knowledge" requirement to mean knowledge of the fraud independent of the public disclosure. *Paranich*, 396 F.3d at 336-37. In other words, the relator would not have learned about the scheme absent the public disclosure. *Id*. In the present case, it would be absurd to conclude that JKJ would not have learned about the scheme absent the public disclosures—which do nothing more than take note of scientific research in which JKJ partner Dr. Gurbel played a pioneering role. SAC ¶¶ 133, 137-41. Moreover, Dr. Gurbel's two journal articles—cited in the Mega Study upon which the *Mills* proposed amended complaint relied—were published in 2003 and 2005, long before the purported 2011 public disclosures in either *Hall* or *Mills* (and the related news articles), and long before the 2008 (and 2009) news articles about the eventual 2009 label change. *U.S. ex rel. Devlin v. California*, 84 F.3d 358, 361 (9th Cir. 1996) ("that the relators had evidence of fraud prior to the public disclosure of the allegations establishes that their knowledge was 'independent'"), *cited with approval in Paranich*, 396 F.3d at 337. The same is true for JKJ partners Stahl and Evans, each of whom endows JKJ with his/her own independent knowledge of the fraud predating the purported disclosures.[33]

[33] Defendants also contend that Relator's use of MDL documents to amend its Complaint precludes Relator from being the original source of "the allegations in the original complaint *as amended*." Defs.' 9/29/17 Mem. at 5, 7-8. Not only are Defendants off the mark (for all the reasons articulated in Relator's Opposition to Defendants' Motion to Strike), Defendants' argument stretches the Supreme Court's decision in *Rockwell Int'l Corp. v. U.S.*, 549 U.S. 457 (2007), to the breaking point. In *Rockwell*, the Court held that the relator could not qualify as an original source of the allegations and theories in the joint (Government and Relator) amended complaint or superseding final pretrial order. *Id.* at 473-76. Nothing in *Rockwell*, therefore, stands for the proposition that a relator must have direct knowledge of every allegation in its complaint. Rather, Relator is only required to have direct knowledge of the central allegations and theory of fraud upon which any recovery is based. *See U.S. ex rel. Simpson v. Bayer Healthcare*, No. 15-2220, 2017 WL 3927021,

B. The Post-PPACA Provision Does Not Bar JKJ's Claims

Since the post-PPACA public disclosure bar is no longer jurisdictional, determination of whether the bar applies is made under Rule 12(b)(6). *See Majestic Blue*, 812 F.3d at 298. As Defendants concede, *see* Defs.' 8/29/17 Mem. at 8-9, under the post-PPACA statute, the *Mills* and *Hall* pleadings did not "issue from a source or occur in a context specifically recognized by the Act," *Paranich*, 396 F.3d at 332, because the FCA now requires that "the Government or its agent" must be a party to the case. *Accord Dickson*, 123 F. Supp. 3d at 598 (under post PPACA provision, the *Hall* complaint was not publicly disclosed). This leaves as public disclosures only the news articles about *Mills*, and the news article(s) about the FDA's eventual 2009 label change.

Under the post-PPACA FCA, the analysis examines whether "substantially the same allegations or transactions as alleged in the [FCA] action or claim were publicly disclosed." 31 U.S.C. § 3730(e)(4)(A), 124 Stat. 119, 901-02 (effective Mar. 23, 2010). Even if news articles concerning the *Mills* plaintiff's complaint qualify as an enumerated source, they fail as public disclosures for the same reasons the proposed *Mills* amended complaint itself failed. In short, the articles merely mention *Mills*' flawed design defect theory—that excessive bleeding was the result of administration to patients with an undefined CYP variant, making them poor metabolizers of Plavix—which is nothing more than a glimpse of the scientific fact about Plavix VOR—which JKJ partner Dr. Gurbel uncovered, while failing to disclose anything concerning Defendants'

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at *2 (8th Cir. Sep. 8, 2017) (applying the *Springfield Terminal* analytical framework to a fraudulent inducement FCA action, and concluding that "to qualify as an original source, a relator does not have to have personal knowledge of all elements of a cause of action. As long as the relator has direct knowledge of the true state of the facts, she can be an original source even though her knowledge of the misrepresentation is not first-hand."). Likewise, nothing in *Rockwell* or *Springfield Terminal* precludes Relator from augmenting its direct knowledge with information obtained from public sources or even from the Defendant itself—especially here where the MDL documents are subject to a Protective Order and therefore cannot be deemed "public disclosures," since they are not—and will not become—available to the public.

decade-long misconduct to conceal, misrepresent and obfuscate the existence or significance of the Plavix VOR issue. *Atkinson*, 473 F.3d at 519; *U.S. ex rel. Purcell v. MWI Corp.*, 824 F. Supp. 2d 12, 23 (D.D.C. 2011) (news articles did not trigger public disclosure bar because they "did not suggest that [defendant] concealed irregular sales commissions in an effort to secure loan money . . . the central allegation at issue here"); *see also Dickson III*, 123 F. Supp. 3d at 599 (*Hall* did not reveal "essential elements of fraudulent scheme" concerning Defendants' scienter).

As to the article(s) discussing the FDA's eventual 2009 label change adding the VOR information, they do not even mention Defendants' failure to disclose the VOR issue, let alone imply that Defendants made actionable misrepresentations concerning VOR. Hence, the article(s) fail to make "substantially the same allegations or transactions" of fraud as set forth in the SAC.

Regardless, under the post-PPACA FCA, JKJ qualifies as an "original source" because it "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions," and "voluntarily provided the information to the Government before filing." 31 U.S.C. § 3730(e)(4)(B)(ii), 124 Stat. 119, 901-02 (effective Mar. 23, 2010); *Dickson III*, 123 F. Supp. 3d at 599. The only change to the provision which needs to be addressed here is whether JKJ's knowledge "materially adds to the publicly disclosed allegations or transactions." Knowledge which "materially adds" is intended to be broader than the prior test requiring "direct" knowledge. *Majestic Blue*, 812 F.3d at 299. Hence, to the extent this Court has already found that JKJ satisfied the prior "direct" knowledge test, it follows that Relator necessarily satisfies the "materially adds" test.

Regardless, the Third Circuit broadly interprets "materially adds" to mean the relator "contribute[s] significant additional information to that which has been publicly disclosed so as to improve its quality." *Id*. at 306. Importantly, *Majestic Blue* rejected the interpretation urged by

Defendants here, Defs.' 8/29/17 Mem. at 9, whereby "original source" status would be precluded whenever the essential elements of the fraud had been publicly disclosed, because "that would read out of the statute the original source exception." *Id.* The court then refocused the analysis, stating "[t]he salient issue, then, is how to distinguish additional but immaterial information from information that 'materially adds' to the publicly disclosed allegations or transactions of fraud." *Id.* The Court then found that relator (a law firm partnership that learned of the fraud through discovery in a wrongful death action) qualified as an original source because it provided additional details as to how the fraud originated and transpired. *Id.*

In the present case, JKJ's allegations provide not only details concerning how the fraud originated and transpired, they provide all the essential elements of the fraud—which were critically missing from the purported public disclosures. *Dickson III*, 123 F. Supp. 3d at 599 (relator materially added to public disclosures concerning Plavix with details concerning defendants' scienter, marketing practices, and impact on government payers). As such, JKJ meets the post-PPACA original source exception to the public disclosure bar.

C. JKJ Continued as the same Entity Notwithstanding a Partner Substitution, and thus is not subject to the FCA's first-to-file bar.

Defendants' speculation, Defs.' 8/29/17 Mem. at 12-13, that Dr. Gurbel's replacement of "Partner B" created a new, separate partnership is wrong as a matter of law and fact.

1. Dr. Gurbel's admission to JKJ did not create a new entity.

JKJ was formed under the Delaware Revised Uniform Partnership Act ("DRUPA") which provides that "relations among partners and between partners and the partnership are governed by the partnership agreement." Del. Code Ann. Tit. 6, § 15-103(a). The JKJ Partnership Agreement ("Agreement") (attached hereto as Exhibit C) provides that the JKJ Partnership "shall not be a

separate legal entity distinct from its Partners."[34] Agreement § 1.03. The Agreement also states that the "withdrawal of a Partner shall not cause a dissolution of the Partnership."[35] *Id.* § 8.01. Indeed, the parties agreed that the "term of the Partnership . . . shall continue until the final resolution or settlement of the Action without further right of appeal." *Id*. § 1.07. Further, the Agreement provides for the admission of a new partner upon the "written consent of the Partners." *Id.* § 7.02.

Pursuant to a Consent of Withdrawal and Admission of Paul Gurbel ("CWAPG") (attached hereto as Exhibit D), the interested individuals allowed "Partner B" to withdraw on December 8, 2016, whereafter the remaining partners consented to the admission of Dr. Gurbel to the partnership as a substitute for "Partner B." *Id*. Because the Agreement controls the legal status of the JKJ Partnership, and it was adhered to, Dr. Gurbel's replacement of "Partner B" did not create a different partnership. Because there was no dissolution of "JKJ-1," there can be no "JKJ-2" as Defendants speculate. Defs.' 8/29/27 Mem. at 12.

Nevertheless, because JKJ is not distinct from its partners, Defendants guess—without support—that Relator follows the "aggregate model" of partnership in order to argue that JKJ ceased to exist. Defs.' 8/29/17 Mem at 13-14. Defendants' conjecture is flawed, however, because the partnership agreement controls, and thus Defendants' construct of "entity model" versus "aggregate model" is irrelevant.[36]

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[34] Although the default rule under DRUPA is that a partnership is a separate legal entity distinct from its partners, a partnership agreement can provide that the partnership is not separate and distinct from the partners. Del. Code Ann. Tit. 6, § 15-201(a). That is precisely what JKJ did.

[35] Section 7.03 permits withdrawal of a partner "(i) upon 60 days prior written notice to the non-withdrawing Partner(s) or (ii) with the written consent of the non-withdrawing Partner(s)."

[36] Defendants' citation to authority for the proposition that the admission of a partner or removal of a partner works a dissolution of the partnership is misplaced. Defs.' 8/29/17 Memo at 14. First, 45 A.L.R. 1240 § I (1926) predates by decades the governing body of law on partnerships applicable here. Indeed, Delaware's Revised Uniform Partnership Act was promulgated to alter

2. JKJ-2 is a Fiction Created by Defendants.

Defendants next venture that "JKJ-2 cannot replace JKJ-1 as a relator" because of the first-to-file bar. Defs' 8/29/17 Mem. at 14. The entire inference of Defendants' analysis is wrong. First, JKJ—the partnership that filed the original complaint—continues to exist. *See supra*. There is no second entity or relator. Notably, Defendants cite no case supporting their supposition that a change in the members of a partnership constitutes an addition or intervention of a new relator. Second, the first-to file rule does not bar relators from voluntarily adding relators to an existing lawsuit. *See infra*. The plain language of the first-to-file rule prohibits only "interven[ing] or bring[ing] a related action." 31 U.S.C. § 3730(b)(5). JKJ has done neither. To the contrary, the same JKJ Partnership filed the original complaint and the two amended complaints. Neither a second JKJ, nor Dr. Grubel has "intervened" in this lawsuit within the meaning of § 3730(b)(5).

III. JOINING JKJ'S INDIVIDUAL PARTNERS ENSURES THE REAL PARTIES IN INTEREST ARE INCLUDED AS RELATORS.

Relator has filed a cross-motion under Rule 17(a)(3), or alternatively Rule 15(a)(2), seeking leave to file an amended complaint joining as relators JKJ's individual partners.

A. Rule 17 Joinder

Rule 17(a)(3), entitled "Joinder of the Real Party in Interest," mandates:

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the common law of partnerships and to prevent the burden of having to reform a new partnership every time a new partner joined or an old partner withdrew. *See generally* Del. Code Ann. Tit. 6, § 15. Second, *Citizens Bank of Mass. v. Parham-Woodman Med. Assoc.*, 874 F. Supp. 705, 708 (E.D. Va. 1995), was decided under the Uniform Partnership Act of Virginia, not the Revised Uniform Partnership Act. Moreover, as that case made clear, even that act altered the common law rule about the dissolution of a partnership because "at common law, admission of a new partner dissolved the old partnership and created a new one." *Id.* at 708. That was no longer true under Virginia law. Third, *Fairway Dev. Co. v. Title Ins. Co. of Minn.*, 621 F. Supp. 120, 123 (N.D. Ohio 1985), was decided under Ohio law, which at that time was modeled after the Uniform Partnership Act, not the Revised Uniform Partnership Act. "Under Ohio Rev. Code § 1775.30, the bankruptcy, expulsion, or death of a partner causes the dissolution of a partnership." *Id.* at 123. The same is not true here, where the partnership is governed by Delaware's Revised Uniform Partnership Act and a partnership agreement promulgated pursuant to the revised partnership act.

> The court may not dismiss an action for failure to prosecute in the name of the real party in interest until, after an objection, a reasonable time has been allowed for the real party in interest to ratify, join, or be substituted into the action. After ratification, joinder or substitution, the action proceeds as if it had been originally commenced by the real party in interest.

Fed. R. Civ. P. 17(a)(3). The rule is designed to "prevent forfeiture of an action when determination of the right party to [bring suit] is difficult or when an understandable mistake has been made." *Gardner v. State Farm Fire & Cas. Co.*, 544 F.3d 553, 563 (3d Cir. 2008). Substitution is proper where the pertinent flaw is merely the identity of the party pursuing the claims and the substitution would correct that pleading defect without altering the facts or issues raised, or unfairly require defendants to litigate against wholly unknown or new parties. *Lefta Associates v. Hurley*, 902 F. Supp. 2d 559, 576-77 (M.D. Pa. 2012) (the Court enjoys broad discretion to permit substitution).

Courts routinely permit substitution of plaintiffs under circumstances similar to those here. *See, e.g.*, *ICON Group, Inc. v. Mahogany Run Development Corp.*, 829 F.2d 473, 477-78 (3d Cir. 1987); *Advanced Magnetics, Inc. v. Bayfront Partners, Inc.*, 106 F.3d 11, 20 (2d Cir. 1997); *Hurley*, 902 F. Supp. 2d at 577; *Boarhead Farm Agreement v. Advanced Environmental Technology Corp.*, 381 F. Supp. 2d 427, 431-33 (E.D. Pa. 2005).

B. Rule 15(a)(2) Amendment

Relator also moves, in the alternative, under Rule 15(a)(2), which states that "[i]n all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The Rule emphasizes that "[t]he court should freely give leave when justice so requires." *Id.* The decision to permit an amendment rests in the sound discretion of the Court. *Heyl & Paterson Int'l Inc. v. F.D. Rich Hous. Of V.I., Inc.*, 663 F.2d 419, 425 (3d Cir. 1981). The Supreme Court has weighed in as follows:

> If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on

> the merits. In the absence of any apparent or declared reason . . . such as **undue delay**, **bad faith** or **dilatory motive** on the part of the movant, **repeated failure to cure deficiencies** by amendments previously allowed, **undue prejudice** to the opposing party by virtue of allowance of the amendment, **futility of amendment**, etc . . . the leave sought, should, as the rules require, be "freely given."

Foman v. Davis, 371 U.S. 178, 182 (1962) (bold added), *cited in Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989) (the non-moving party's ability to carry its burden of showing prejudice "is the touchstone" for denying an amendment). Here, the proposed amendment substituting JKJ's partners as relators is not the product of bad faith or dilatory motive. JKJ had a reasonable basis to believe it had standing and the requisite "direct" knowledge to maintain this action. Furthermore, a mere substitution of the individual partners who have the same inchoate statutory interest under the FCA that JKJ purported to possess, will not delay or prejudice Defendants at all. It will only change to whom the statutory reward is paid. *Bechtel*, 886 F.2d at 652 (to show prejudice the non-moving party "must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the … amendments been timely").

Furthermore, the Court has not ruled on any motions challenging the sufficiency of Relator's pleadings, nor previously afforded Relators an opportunity to cure those deficiencies. Finally, without a ruling by the Court that the legal theory is irretrievably flawed, there is no basis upon which to find that amendment would be futile. *Glassman v. ComputerVision Corp.*, 90 F.3d 617, 623 (1st Cir. 1996) ("[f]utility means that the complaint, as amended, would fail to state a claim upon which relief could be granted"). In the present case Defendants do not argue JKJ's individual partners lack standing. Moreover, Defendants implicitly concede that JKJ's individual partners satisfy the FCA's original source criteria. Therefore, Defendants will not be able to carry their burden of showing that the amendment is futile.

C. The Proposed Amendment Relates Back

Whether via amendment under Rule 15(a), or upon proper ratification, joinder or substitution under Rule 17, "the action should proceed as if properly filed initially." *ICON*, 829 F.2d at 478. The Rules note the interplay between the relation back in Rules 17(a) and 15(c) as follows:

> The relation back of amendments changing plaintiffs is not expressly treated in revised Rule 15(c) since the problem is generally easier. Again, the chief consideration of policy is that of the statute of limitations, and the attitude taken in revised Rule 15(c) toward change of defendants extends by analogy to amendments changing plaintiffs. Also relevant is the amendment of Rule 17(a) (real party in interest). To avoid forfeitures of just claims, revised Rule 17(a) would provide that no action shall be dismissed on the ground that it is not prosecuted in the name of the real party in interest until a reasonable time has been allowed for correction of the defect in the manner there stated.

Fed. R. Civ. P. 15, Advisory Comm. Note to 1966 Amendments; *Gatto v. MacMillan, M.D.*, No. 96-cv-2910, 1997 WL 22393 (E.D. Pa. Jan. 21, 1997) (applying Rule 15(c) analysis to Rule 17(a) motion); *see Nelson v. County of Allegheny*, 60 F.3d 1010, 1014-15 and nn.7-8 (3d Cir. 1995).

Upon a joinder motion, the Third Circuit applies the two-prong test reflected in Rule 15(c) for relation back, inquiring whether the defendants "received such notice that they will not be prejudiced in maintaining a defense on the merits," and whether the defendants "knew or should have known that, but for a mistake concerning the identity of the proper party, the action would have been brought with the original claims." *Nelson*, 60 F.3d at 1014. Where, as here, the plaintiff merely seeks to substitute the real parties in interest, the substitution "is not significant when the change is merely formal and in no way alters the known facts and issues on which the action is based." *See id.*, 60 F.3d at n.8 (parenthetically quoting *Staren v. American Nat. Bank & Trust Co.*, 529 F.2d 1257, 1263 (7th Cir. 1976), and citing 6A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1501 (1990) (citing cases permitting amendments that substitute new plaintiffs to relate back if the added plaintiffs are real parties in interest)).

Here, the first prong is satisfied because the proposed amended complaint is identical to the SAC, except for the addition of JKJ's individual partners as relators. Hence, Defendants will not be prejudiced in maintaining a defense on the merits because they already had notice of the precise allegations. *Id.* at 1014-15 ("The 'prejudice' to which the Rule refers is that suffered by one who, for lack of timely notice that a suit has been instituted, must set about assembling evidence and constructing a defense when the case is already stale.") (internal quotation and citation omitted).

The second prong is satisfied because JKJ had a reasonable basis, based upon case law and the fact it is a Delaware partnership which is not a separate legal entity distinct from its partners, that it had standing to bring this action and was endowed with its partners' knowledge enabling it to satisfy the FCA's "direct" knowledge criteria. *See Precision II*, 31 F.3d at 1017 (permitting corporate relator to amend and add shareholder relators, after corporate relator was found not to have "direct" knowledge).

D. The Amended Complaint Does Not Impermissibly Create Jurisdiction.

Defendants argue that, "[b]ecause JKJ cannot be a relator," this Court "has lacked jurisdiction over JKJ's pre-PPACA claims" and therefore this Court should deny Relator's motion. Defs.' 8/29/17 Mem. at 17-19. Not so. In addition, Defendants' embrace the Fifth Circuit's opinion in *Federal Recovery Serv., Inc. v. United States*, 72 F.3d 447 (5th Cir. 1995), as if it is controlling precedent, Defs.' 8/29/17 Mem. at 18-19. It is not.

To the contrary, courts in this Circuit follow *Precision II*, where the Tenth Circuit squarely rejected defendants' identical argument that "if jurisdiction is lacking at the commencement of [a] suit, it cannot be aided by the intervention of a [plaintiff] with a sufficient claim." *Id*. at 1019 (internal quotation and citation omitted), *cited in U.S. ex rel. Boise v. Cephalon, Inc.*, No. 08-287,

2014 U.S. Dist. LEXIS 144056 at *10 (E.D. Pa. Oct. 9, 2014); *see Rockwell Int'l Corp. v. U.S.*, 549 U.S. 457, 474 (2007) ("courts look to the amended complaint to determine jurisdiction").

Furthermore, it is beyond dispute that JKJ can add the individual partners as relators because post-PPACA original source status is not jurisdictional.

E. The First-to-File Bar Does Not Prohibit Substitution or Joinder.

Courts in the Third Circuit and elsewhere have held that the FCA's first-to-file rule[37] does not apply to the voluntary addition of relators by amended complaint in a pending action. *See Boise*, 2014 U.S. Dist. LEXIS 144056, at *9. Judge O'Neill's decision in *Boise* is instructive. There, after Boise amended his original complaint to add two relators, Augustine and DuFour, defendant argued that the first-to-file bar prevented their voluntary joinder. *Id.* at *4-*5. The court disagreed holding that "the first-to-file rule does not apply to the voluntary addition of relators by amended complaint where relators have entered into a private agreement regarding the division of potential proceeds from the action." *Id.* at *9. The *Boise* court's rationale was threefold.

First, adopting the Tenth Circuit's statutory analysis in *Precision II*, the *Boise* court found that section 3730(b)(5)'s term "intervene" must be given its plain meaning, consistent with that meaning of "intervene" as used in Rule 24. *Boise*, 2014 U.S. Dist. LEXIS 144056 at *10; *see* Fed. R. Civ. P. 24. "Congress intended only to ban the addition of relators who were 'strangers' to the plaintiff, since a Rule 24 'intervenor need not have a relation to the original plaintiff to intervene in an action.'" *Id.* at *6 (quoting *Precision II*, 31 F.3d at 1017); *see also U.S. ex rel. Ramsey*, No. 1:08-cv-133, 2012 U.S. Dist. LEXIS 189752, at *11 (S.D. Ind. June 4, 2012) (holding that "the term 'intervene' as used in 31 U.S.C. § 3730(b)(5) means intervention of the types set forth in Rule

[37] "When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5).

24"); *U.S. ex rel. Bumbury v. Med-Care Diabetic & Med. Supplies, Inc.*, No. 10-81634-CIV, 2014 U.S. Dist. LEXIS 193651, at *23-24 (S.D. Fla. Dec. 23, 2014) (same). Moreover, "it is unambiguous that a relator does not bring a later and separate 'related action' under § 3730(b)(5) when he or she joins an existing action through an amended complaint." *Id.* at *10.

Second, policy considerations support reading § 3730(b)(5) to allow the addition of relators by amended complaint. *Boise*, 2014 U.S. Dist. LEXIS 144056 at *11. Section 3730(b)(5) was enacted to address concerns about claimants alleging the same material facts as prior relators and demanding a share of the *qui tam* award even though the new relator's allegations were unlikely to increase the total recovery. *Id.* at *11. "The same fairness concerns are not present where, as here, plaintiffs have consented to join together and share any proceeds of their suit due to the real or perceived advantage the additional relators bring to the complaint." *Id.* at *11-12 (internal citations omitted); *see also U.S. ex rel. Howard v. Lockheed Martin Corp.*, No. 99-cv-285, 2011 U.S. Dist. LEXIS 106203, at *12 (S.D. Oh. Sept. 16, 2011).

Third, the district court in *Boise* found its holding to be consistent with Third Circuit precedent. *Id.* at *12 (citing *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 230 (3d Cir. 1998)). In *LaCorte*, the Third Circuit noted the voluntary addition of relators to an existing FCA action without disapproval.[38] *Id.* at 230.

Notably, the *Boise* court also rejected the reasoning of cases relied on by Defendants here. In particular, *Boise* rejected the analysis of *U.S. ex rel. Fry v. Guidant Corp*., No. 03-0842, 2006 U.S. Dist. LEXIS 29862, 2006 WL 1102397 (M.D. Tenn. April 25, 2006) and *U.S. ex rel. Manion v.*

[38] There, the original complaint was filed in November 1993 in Pennsylvania and an additional relator from Texas joined that action in December. *LaCorte*, 149 F.3d at 230-31. The Third Circuit in that case affirmed the District Court's dismissal of several newly filed *qui tam* complaints filed *after* a proposed settlement agreement was reached between the government and the Defendant in the already pending actions. *Id*. at 231, 238.

St. Luke's Reg'l Med. Ctr., Ltd., No. 06-498, 2008 U.S. Dist. LEXIS 25719, 2008 WL 906022, at *7 (D. Idaho Mar. 31, 2008), as misreading controlling Fourth Circuit and Ninth Circuit precedent. *Boise*, 2014 U.S. Dist. LEXIS 144056, at *10-11.

Although Defendants marshal a smattering of district court cases to claim that the "weight of authority" favors them, Defs.' 8/29/17 Mem. at 15, this is simply false. To the contrary, most courts addressing this issue have held that the first-to-file bar does not prohibit a relator from voluntarily adding another relator. *See, e.g., Precision II*, 31 F.3d at 1017 ("the [first-to-file bar] implies intervention of the types set forth in Rule 24(b)(2), and the addition of parties does not constitute intervention")[39]; *U.S. v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 459 (W.D. Pa. 2012) ("[t]he plain text of § 3730(b)(5) does not apply … because [the added relator] is not 'intervening' or bringing a 'related action'"); *see also U.S. v. Space Coast Med. Assocs., L.L.P.*, No. 6:13-cv-1068-ORL-22TBS, 2014 U.S. Dist. LEXIS 195931, at *7 (M.D. Fla. Oct. 22, 2014) (same); *U.S. ex rel. Sanders v. E. Alabama Healthcare Auth.*, 953 F. Supp. 1404, 1408 (M.D. Ala. 1996) (same).

Many of Defendants' inapposite cases reflect the minority view that strangers who file separate *qui tam* actions with similar allegations to an earlier-filed FCA suit cannot defeat the first-to-file bar by agreeing to consolidate the separate actions.[40] That is not the situation presented here.[41] Even further afield is Defendants' reliance on *U.S. ex rel. Piacentile v. Sanofi Synthelabo,*

[39] Although earlier in their brief Defendants rely on *Precision I* to argue that JKJ, as a partnership, cannot be an original source, Defs.' 8/29/17 Mem. at 7, they remain silent as to *Precision II* where the Tenth Circuit held that the corporation could remedy that perceived issue by joining the individual stockholders. 31 F.3d at 1017.

[40] *See U.S. ex rel. Carson v. Manor Care, Inc.*, 851 F.3d 293, 305 (4th Cir. 2017); *U.S. ex rel. Rush v. Agape Senior, LLC*, No. 3:13-cv-00666-JFA, 2014 U.S. Dist. LEXIS 174206, at *17-19 (D. S.C. Aug. 18, 2014); *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2012 U.S. Dist. LEXIS 118159, at *9-10 (D. N.J. Aug. 21, 2012); *U.S. ex rel. Denenea v. AllState Ins., Co.*, No. 07-2795, 2011 U.S. Dist. LEXIS 6419, at *7-8 (E.D. La. Jan. 24, 2011).

[41] Moreover, Defendants reliance on *U.S. ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001), is inapposite because it did not address the scenario presented here. In that

Inc., No. 05-2927 (KSH), 2010 U.S. Dist. LEXIS 13785 (D. N.J. Dec, 30, 2010). In that case, Piacentile's *qui tam* case was barred by the first-to-file rule because three years earlier another relator, Gohill, had filed a FCA case alleging substantially the same facts against defendants, and Gohill's case was still pending when Piacentile filed his suit.[42] *Id.* at *9-16.

Voluntary joinder is in complete harmony with 3730(b)(5)'s two-fold purpose of protecting the government's interest. First, by barring intervention or a separate suit, the rule prevents interlopers from weakening a whistleblower's incentive to come forward by divesting the original whistleblowers stake in the case. *U.S. ex rel. Chovanec v. Apria Healthcare Group Inc.*, 606 F.3d 361, 364 (7th Cir. 2010). Allowing JKJ to add its partners as relators presents no such risk.

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case, the Court determined that an earlier-filed complaint that was eventually dismissed after a second case was filed still barred the later-filed action. *Id.* Central to the Court's holding was that the earlier complaint constituted a "pending action" because it was pending when the subsequent relator brought her claim. *Id. Boise* expressly rejected the notion that *Lujan* conflicted with *Precision II* and Boise's own analysis. *Boise*, 2014 U.S. Dist. LEXIS 144056 at *10-11. Likewise, in *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 28-29 (1st Cir. 2009), the affirmance of the lower court's dismissal of certain claims never reached whether a relator could be added without violating the first-to-file rule. The district court's decision to prevent the addition of a relator was nothing more than *dicta*. *See U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 551 F. Supp. 2d 100, 102, 110 (D. Mass. 2008). Although *U.S. ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.*, No. cv 06-498-S-EJL, 2008 U.S. Dist. LEXIS 25719, at *7 (D. Idaho Mar. 31, 2008), held that a relator could not add a relator by amendment, it rejected the Tenth Circuit's holding permitting voluntary additions as articulated in *Precision II,* 31 F.3d at 1017-18, under the false impression that to do so would require a departure from Ninth Circuit law with respect to 31 U.S.C. § 3731 as set forth in *Lujan*. *Manion*, 2008 U.S. Dist. LEXIS 25719, at *19. However, as discussed above, *Lujan* did not involve a relator amending a complaint to voluntarily add a relator.

[42] Defendants also rely on *Palladino ex rel. U.S. v. VNA of S. N.J., Inc.*, 68 F. Supp. 2d 455, 477 (D. N.J. 1999), where the district court concluded that the new relator brought a "related action based on facts underlying the pending action." *Id*. at 478. The parties did not raise, and the court did not address, the issue presented here: whether the voluntary addition of a new relator to an existing lawsuit is barred by the first-to-file rule. To the extent it implicitly came to that conclusion, its holding contradicts controlling precedent in that Third Circuit. *See St. John LaCorte*, 149 F. 3d at 230-31. Relator respectfully states that the District of New Jersey erred in its application of the rule articulated in *LaCorte*, 149 F.3d at 231, to the facts before it, and urges this Court to follow the more recent decisions of the federal courts cited herein.

Second, the rule is intended to prevent parasitic lawsuits resulting in multiple whistleblower bounties. *Id.*; *see also U.S. ex rel. Fisher v. Homeward Residential Inc.*, No. 4:12-cv-461, 2015 U.S. Dist. LEXIS 78636, at *13 (E.D. Tx. June 17, 2015). An amendment to add relators does not run afoul of these goals. In the present case, Defendants are not at risk for multiple or inconsistent judgments by the addition of new relators because the individual partners have reached a private agreement with regards to any potential recovery.[43]

Here, the facts supporting joinder are compelling. First, as in *Precision II*, Relator seeks to add the principals of JKJ—not strangers. Second, the underlying facts and the people/entities involved remain the same; only the names of the parties would change. Third, Defendants would not be prejudiced by their addition because Defendants knew who they were when the SAC was filed. Fourth, the parties are in the early stages of this litigation and Defendants have yet to file an answer. Fifth, joinder of all real parties in interest increases judicial efficiency.

CONCLUSION

Defendants' Motion to Dismiss should be denied. In the event the Court finds that JKJ cannot maintain this action because it lacks standing, does not qualify as an "original source," or for any other reason, JKJ respectfully submits that the Court should grant its alternative Cross-Motion to substitute JKJ's individual partners as relators.

[43] Of course, JKJ could have joined as co-relators *ab initio*. *See, e.g.*, *Kennard v. Comstock Resources, Inc.*, 363 F.3d 1039 (10th Cir. 2004) (first relator solicited second relator to investigate facts of suspected fraud and then filed suit); *U.S. ex rel. Kennedy v. Aventis Pharm.*, 512 F. Supp. 2d 1158, 1167 (N.D. Ill. 2007) (two pharmaceutical sales representatives observed separate evidence of off-label marketing and joined as co-relators). The timing of joinder should not bar the individual partners or their claims given that the FCA suit exists.

Dated: September 19, 2017

Respectfully submitted,

/s/ Gerald C. Robinson
W. Scott Simmer*
Gerald C. Robinson, NJ Lic. 028452005
Andrew M. Miller*
SIMMER LAW GROUP PLLC
600 New Hampshire Ave., Ste 10-A
Washington, DC 20037
Telephone: (202) 333-4562
Fax: (202) 337-1039
scott.simmer@simmerlaw.com
gerald.robinson@simmerlaw.com
andrew.miller@simmerlaw.com

William H. Narwold*
Michael J. Pendell*
Laura W. Ray*
MOTLEY RICE LLC
One Corporate Center, 20 Church St., 17th Flr
Hartford CT 06103
Telephone: (860) 882-1676
bnarwold@motleyrice.com
mpendell@motleyrice.com
lray@motleyrice.com

Nathan D. Finch*
MOTLEY RICE LLC
3333 K St. NW, Suite 450
Washington DC 20007
Telephone: (202) 232-5507
nfinch@motleyrice.com

Counsel for Plaintiff-Relator JKJ Partnership 2011 LLP

*Admitted *pro hac vice*

CERTIFICATE OF SERVICE

I hereby certify that on September 19, 2017, at the Court's specific direction, I caused a true and correct copy of the following:

1. Plaintiff-Relator's Combined Memorandum: In Opposition to Defendants' (Third) Motion to Dismiss Relators Second Amended Complaint; and in Support of Plaintiff-Relator's Cross-Motion for Leave to File Third Amended Complaint, complete with all Exhibits referenced therein; and
2. Supporting Declaration of W. Scott Simmer,

to be served via electronic mail upon the following counsel of record:

Anand Agneshwar, anand.agneshwar@apks.com
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55TH Street
New York, NY 10019-9710

Drew A. Harker, drew.harker@apks.com
Daniel S. Pariser, daniel.pariser@apks.com
David D. Fauvre, david.fauvre@apks.com
Murad Hussain, murad.hussain@apks.com
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, N.W.
Washington, D.C. 20001

Gavin J. Rooney, grooney@lowenstein.com
Naomi D. Barrowclough, nbarrowclough@lowenstein.com
LOWENSTEIN SANDLER LLP
65 Livingston Avenue
Roseland, NJ 07068

I further certify that on September 19, 2017, I caused a true and correct copy of the foregoing pleadings to be served, via United States mail, first class postage prepaid, upon:

Jefferson Sessions, US Attorney General
U.S. Department of Justice
950 Pennsylvania Ave, NW
Washington, DC 20530-0001

Paul J. Fishman, US Attorney
Office of the US Attorney
970 Broad St, Ste 700
Newark, NJ 07102

Lucy E. Muzzy, Asst. US Attorney
Office of the US Attorney
970 Broad St, Ste 700
Newark, NJ 07102

Charles S. Graybow
Office of the US Attorney
970 Broad St, Ste 700
Newark, NJ 07102

Raymond J. Liddy, Deputy Atty. General
Office of the Attorney General
California Department of Justice
1455 Frazee Road, Ste 315
San Diego, CA 92108

George A. Codding, Sr. Asst. Atty Gen
Colorado Department of Law
Office of the Attorney General, MFCU
1300 Broadway, 9th Fl
Denver, CO 80203

Robert B. Teitelman, Asst. Atty Gen
Office of the Attorney General
55 Elm St
Hartford, CT 06106-1774

Kate Keller, MFCU Director
Office of the Attorney General
820 N French St, 5th Fl
Wilmington, DE 19801

Jane Drummey, Asst. Atty Gen
Office of the Attorney General
Civil Enforcement Section, Civil Litigation Division
441 Fourth St, Ste 650 North
Washington, DC 20001

James D. Varnado, MFCU Director
Office of the Attorney General
PL-01 The Capitol
Tallahassee, FL 32399

Jeffrey H. Atwater, Chief Financial Officer
Department of Financial Services
Division of Consumer Services
200 East Gaines St
Tallahassee, FL 32399-0300

Nancy B. Allstrom, Sr. Asst. Atty Gen
Medicaid Fraud Control Unit
200 Piedmont Ave. SE
West Tower, 19th Fl
Atlanta, GA 30334

Patrick Keenan, Medicaid Fraud Bureau Chief
Office of the Attorney General
100 W. Randolph St, 12th Fl
Chicago, IL 60601

Curtis Hill, Atty Gen
Office of the Attorney General
Indiana Government Center South
302 W. Washington St, 5th Fl
Indianapolis, IN 46204

Lori Torress, Inspector General
Office of the Inspector General
315 W. Ohio St, Rm. 104
Indianapolis, IN 46202

Nicholas Diez, Asst. Atty Gen
Office of the Attorney General
1885 N. 3rd St
Baton Rouge, LA 70802

Maura Healey, Atty Gen
Office of the Attorney General
One Ashburton Place
Boston, MA 02108

David E. Tanay, MFCU Director
Office of the Attorney General
2860 Eyde Parkway
East Lansing, MI 48823

Lori Swanson, Atty Gen
Office of the Attorney General
1400 Bremer Tower
445 Minnesota St
St. Paul, MN 55101-2131

Kenneth E. Varns, Asst. Atty Gen
Montana Department of Justice
215 North Sanders
PO Box 201401
Helena, MT 59620-1401

Joshua Lichtblau, Asst. Atty Gen
Office of the Attorney General
25 Market St, PO Box 080
Trenton, NJ 08625-0080

Jacob M. Bergman, Asst. Atty Gen
Medicaid Fraud Control Unit
Office of the Attorney General
120 Broadway, 12th Fl
New York, NY 10271

Mark N. Kemberling, MFCU Director
Office of the Attorney General
555 East Washington Ave., Ste. 3900
Las Vegas, NV 89101

Steven K. McCallister, Asst. Atty Gen
Office of the Attorney General
Department of Justice, Medicaid
Investigations Unit
5505 Creedmoor Rd., Ste 300
Raleigh, NC 27612

Niki S. Batt, Asst. Atty Gen
Medicaid Fraud Control Unit
Office of the Attorney General
313 NE 21st St
Oklahoma City, OK 73105

James Dube, MFCU Director
Office of the Attorney General
150 S. Main St
Providence, RI 02903

Mary McCullohs, Asst. Atty Gen
Office of the Attorney General
PO Box 20207
Nashville, TN 37202

Mark Herring, Atty Gen
Office of the Attorney General
900 East Main St
Richmond, VA 23219

Timothy Samuelson, MFCU Director
Office of the Attorney General
PO Box 7857
Madison, WI 53707-7857

Dated September 19, 2017

By: */s/ Gerald C. Robinson*
Gerald C. Robinson (NJ Bar No. 028452005)
SIMMER LAW GROUP, PLLC